REMARKS/ARGUMENTS

Claims 1-6 are pending in this application. Claims 7-22 have been wiuthdrawn from consideration. Claims 1-6 have been rejected.

Claim 1 has been amended. It is respectfully submitted that the amended claim are fully supported in the specification as filed and that no new matter has been added. Support for the amendments to claim 1 is found in the specification as filed at page 4 line 27-page 5 line 3 (for samples not previously treated with a cell lysing reagent) and page 10, line 5-6 (for wherein sample is admixed with a buffer).

Information Disclosure Statement

Applicants note that the Examiner has communicated that the IDS received on March 2, 2004 has not been considered as it does not comply with the requirements of 37 CFR 1.98(a)(iii), in that the rule requires that for each cited pending US application, the application specification including the claims, and any drawing of the application, or that portion of the application that caused it to be listed including any claims directed to that portion be provided, and that each US application listed in an IDS must be identified by the inventor, application and filing date.

Applicants will provide a corrected IDS as a separate mailing.

Drawings

The Examiner has indicated the Drawings are acceptable.

Specification

The specification was objected as the Examiner avers that on page 38 Applicants appear to disclose a comparison of the DNA extracted from white blood cells (WBC) between the method involving the use of a lysing reagent (control) and the method of the instant invention, further averring that while the (comparative) method of extracting DNA via use of a lysing reagent is discussed in detail, the method involving the instant invention is not disclosed, further citing the description at page 38 entitled "Method of Invention - No Use of Lysing Agent", and further averring that the specification states that samples not contacted with lysis reagent were treated as follows: the pellet from each of the four separate tubes was resuspended in 100 µl of PBS. The Examiner concludes that it appears the description of the instant invention is missing.

Applicants point out that the essence of the invention is indeed the rapid and efficient capture of DNA from sample *without using a lysing reagent*. There is no description missing nor is there a failure of disclosure of the instant invention. The citation at page 38 is complete. Where the methods of the instant

invention are employed, there is no sample preparation employing a lysis step. The sample is simply resuspended in buffer and admixed with the weakly basic polymer. It is respectfully submitted that the specification is complete and that this objection be withdrawn.

Rejection Under 35 USC § 112

Claims 1-6 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

In particular, the Examiner avers that claim 1 is indefinite for reciting the phrase "without the use of cell lysing reagent", because it is unclear how nucleic acids, which are enclosed in a cell membrane (whether prokaryotic or eukaryotic) could be extracted without first disrupting the cell membrane, hence the Examiner avers, all reagents must first lyse the cell, and the Examiner asks for clarification.

Applicants point out that all that is required under this invention is contacting the sample in buffer at a pH at about 7 with a water-soluble weakly basic polymer as claimed. Indeed it is the advancement of the instant invention that no prior extraction of nucleic acids is necessary before contacting the sample with the aforesaid weakly basic polymer. See specification at page 9 lines 15-17, and page 10, lines 5-14. This is an advancement

over the prior art which disclosed separation of the nucleic acid from the sample (page 3 lines 4-14). In light of these arguments Applicants request this rejection be withdrawn.

Claim 1 was also rejected as indefinite for reciting the phrase "ethylenically unsaturated" because it is averred it is unclear what is meant by this phrase. Applicants point out that this phrase refers to the nature of the polymerizable monomer employed in the invention, which monomer is depicted structurally at page 16, line 5; an alternative structure of the monomer appears at page 17, line 10. In each case the Examiner's attention is directed to the CH_2=C double bond, which is an ethylene group that by virtue of its double bond is considered to be chemically unsaturated. It is respectfully submitted that one having skill in the chemical arts and in particular in the polymer chemistry arts to which this invention pertains would be familiar with this term. For this reason it is respectfully submitted the term is not indefinite but clear, and therefore Applicants request this rejection be withdrawn.

Claim 1 was further found indefinite for reciting the phrase "method for providing a nucleic acid from a sample without use of a cell lysing reagent comprising the steps of . . . at a pH less than 7, contacting a sample . . . with a water-soluble, weakly basic polymer . . ." because it is unclear what element actually comprises pH of less than 7. The Examiner has stated,

with reference to the specification at page 10, second paragraph, that a sample (suspected of containing a nucleic acid) is admixed *with a buffer at below pH of about 7.0*, and thus has accepted this interpretation for the purposes of prosecution.

The Examiner has indeed interpreted the claim correctly and applied a relevant portion of the specification. Applicants have herein amended claim 1 to clarify that the sample is admixed in buffer. Therefore, it is respectfully submitted that this rejection be withdrawn.

Rejection Under 35 USC 102(b)

Claims 1-6 were rejected under 35 U.S.C. § 102(b) as being anticipated by Backus et al. (U.S. Pat. No. 5,582,988, issued December 10, 1996).

The Examiner avers that preliminarily the claim is rejected on the interpretation that the claim is drawn to providing a nucleic acid from a sample without use of a cell lysing reagent, comprising the recited steps (A), (B), and (C) of claim 1, that the claim does not limit what is embraced by the term "sample", and thus so long as the nucleic acid is provided from a sample without the use of a lysing reagent, comprising the recited steps, prior art would properly anticipate the invention as claimed. The Examiner continues that the method disclosed by Backus et al. provides nucleic acid from a

cell lysate, which is also embraced by the general term "sample", employed by the instant claims, wherein the method employs non-lysing reagents. The Examiner has cited portions of Backus et al. that are deemed relevant to the rejection.

Applicants traverse the rejection for the following reasons.

The instantly claimed invention is directed to use of a weakly basic polymer for binding and subsequent releasing of DNA contained in *a sample that has not been previously treated with a cell lysing reagent.* This aspect of the invention has been recited in claim 1 see page 53 lines 4-5, (also refer to specification at page 4 line 15 - page 5 line 3). The advancement of the instant claimed invention, claimed in particular in claim 1, is that no extraction of nucleic acids from a sample (in buffer) is required prior to contact of the sample with the weakly basic polymer. See specification at page 9, lines 15-18. As claims 2-6 all depend on claim 1, the limitations of claim 1 are read thereon.

The Applicants need not be limited in reciting the nature of the sample, indeed the sample has been recited as being typically blood or serum (specification at page 4, lines 15-18) but may include other samples not previously treated with cell lysing reagents, including other body fluids including but not limited to urine, bile, spinal fluid, bronchial lavage (BAL), colonic

washes, and stool (specification at page 4 line 27 - page 5 line 3). In addition, samples of any type can be used, including those collected from animals, humans, environmental and microbial specimens (see specification at page 4 line 27-page 5 line 3). It is further recited that the "sample" may include "a sample of any type collected from animals, humans, environmental or microbial specimens" may be used (see specification at page 8 lines 9-11). Further it is recited that "Test specimens ("samples") can include body fluids or other materials containing genetic DNA or RNA. The target nucleic acid can be extracted from any suitable human, animal, microbial, viral or plant source." (see specification at page 9 lines 11-13).

It is clear from claim 1 (page 53, lines 4-5) that the nucleic acid is provided from a "sample" without the use of a cell lysing reagent. To make this even more clear and to further distinguish claim 1 from Backus et al., and in the interest of further prosecution of the claims, Applicants have amended claim 1 to recite the sample is not previously treated with a cell lysing reagent, citing the specification at page 4, line 27-page 5, line 3 in support thereof.

In contrast to Applicants claim 1, the sample in Backus is a "lysate", a sample previously treated with a cell lysing reagent such as for example a surfactant. The fact that Backus et al. employs a lysing step is demonstrated by disclosure in the '988 patent at col. 4

lines 19-43, and col. 16 line 15-65. In the latter passage, it is stated that low copy HIV1 target proviral DNA was extracted from the 8E5/LAV cell line using conventional procedures, then subjected to cell lysis and digestion steps. Further, Backus et al. at Example 3 lines 45-57 discloses using samples of urine specimens which were mixed with buffer solution containing the non-ionic surfactant Tween 20®.

In light of the foregoing amendment to claim 1 and argument distinguishing claim 1 from Backus et al., Applicants respectfully request that claims 1-6 are patentable over Backus et al. and that this rejection be withdrawn.

For the above-stated reasons and in light of Applicants' amendments made herein, it is respectfully submitted that the claims are patentable over the rejections and art cited. Applicants therefore respectfully request that the rejections be withdrawn and the claims be allowed.

Please charge the fees due in connection with the filing of this Amendment to Deposit Account No.10-0750/CDS0219USPCT/CKG in the name of Johnson & Johnson.

Respectfully submitted,

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DATE: December 20, 2005

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